

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BOARD OF REGENTS, THE UNIVERSITY OF
TEXAS SYSTEM, and TISSUEGEN. INC.,

Plaintiffs,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

C.A. No. 18-392-MN

JURY TRIAL DEMANDED

ANSWER OF DEFENDANT BOSTON SCIENTIFIC CORPORATION

1. Defendant Boston Scientific Corporation, by and through its undersigned counsel, answers the Complaint of Board of Regents, the University of Texas System (“UT”) and TissueGen, Inc. (“TissueGen”) as follows:

I. THE PARTIES

2. Defendant lacks knowledge or information regarding the allegations of the first two sentences of paragraph 2 and, therefore, denies those allegations. Defendant denies the allegations of the last sentence of paragraph 2.

3. Defendant lacks knowledge or information regarding the allegations of paragraph 3 and, therefore, denies the allegations of this paragraph.

4. Defendant denies the allegations of paragraph 4, except that Defendant admits that it is a Delaware corporation with a principal place of business at 300 Boston Scientific Way, Marlborough, Massachusetts 01752.

II. JURISDICTION AND VENUE

5. Defendant admits that Plaintiff purports to bring this action under 35 U.S.C. § 1 et seq. and purports to assert subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Defendant denies the allegations of paragraph 6 except that Defendant lacks knowledge or information regarding the allegation that UT is an arm of the State of Texas and, therefore, denies that allegation.

7. Defendant denies the allegations of paragraph 7.

8. Defendant denies the allegations of paragraph 8 except that Defendant admits that the United States District Court for the District of Delaware has jurisdiction over Boston Scientific.

9. Defendant denies the allegations of paragraph 9.

10. Defendant denies the allegations of paragraph 10.

III. TISSUEGEN'S FOUNDATION

11. Defendant lacks knowledge or information regarding the allegations of paragraph 11 and, therefore, denies the allegations of this paragraph.

12. Defendant lacks knowledge or information regarding the allegations of paragraph 12 and, therefore, denies the allegations of this paragraph.

13. Defendant lacks knowledge or information regarding the allegations of paragraph 13 and, therefore, denies the allegations of this paragraph.

14. Defendant lacks knowledge or information regarding the allegations of paragraph 14 and, therefore, denies the allegations of this paragraph.

15. Defendant lacks knowledge or information regarding the allegations of paragraph 15 and, therefore, denies the allegations of this paragraph.

16. Defendant lacks knowledge or information regarding the allegations of paragraph 16 and, therefore, denies the allegations of this paragraph.

17. Defendant lacks knowledge or information regarding the allegations of paragraph 17 and, therefore, denies the allegations of this paragraph.

18. Defendant lacks knowledge or information regarding the allegations of paragraph 18 and, therefore, denies the allegations of this paragraph.

19. Defendant lacks knowledge or information regarding the allegations of paragraph 19 and, therefore, denies the allegations of this paragraph.

20. Defendant lacks knowledge or information regarding the allegations of paragraph 20 and, therefore, denies the allegations of this paragraph.

IV. COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,596,296 B1

21. Defendant repeats and re-alleges its answers to every allegation of the prior paragraphs as though set forth fully herein.

22. Defendant denies the allegations of paragraph 22, except that Defendant admits that the '296 Patent—titled “Drug Releasing Biodegradable Fiber Implant”—was issued on July 22, 2003, by the United States Patent and Trademark Office to named inventors Kevin D. Nelson, Andres A. Romero-Sanchez, George M. Smith, Nadir Alikacem, Delia Radulescu, Paula Waggoner, and Zhibing Hu, that the Board of Regents, The University of Texas System, is identified as assignee, and that a copy of the '296 Patent is attached to the Complaint as Exhibit A.

23. Defendant lacks knowledge or information regarding the allegations of paragraph 23 and, therefore, denies the allegations of this paragraph.

24. Defendant denies the allegations of paragraph 24, except that Defendant avers that the '296 Patent speaks for itself and refers the Court to the patent for its contents.

25. Defendant denies the allegations of paragraph 25.

26. Defendant denies the allegations of paragraph 26.

27. Defendant denies the allegations of paragraph 27.

28. Defendant denies the allegations of paragraph 28.

29. Defendant denies the allegations of paragraph 29, including the claim chart attached to the Complaint as Exhibit B.

A. MONORAIL™ CATHETER PRODUCTS

30. Defendant denies the allegations of paragraph 30, except that Defendant admits that at least one of the Monorail™ Catheter Products comprises a bioabsorbable polymer.

31. Defendant denies the allegations of paragraph 31.

32. Defendant denies the allegations of paragraph 32.

33. Defendant denies the allegations of paragraph 33.

34. Defendant denies the allegations of paragraph 34.

35. Defendant denies the allegations of paragraph 35.

36. Defendant denies the allegations of paragraph 36.

37. Defendant denies the allegations of paragraph 37.

38. Defendant denies the allegations of paragraph 38.

39. Defendant denies the allegations of paragraph 39.

B. SYNERGY™ OVER-THE-WIRE PRODUCTS

40. Defendant denies the allegations of paragraph 40.

41. Defendant denies the allegations of paragraph 41.

42. Defendant denies the allegations of paragraph 42.

43. Defendant denies the allegations of paragraph 43.

44. Defendant denies the allegations of paragraph 44.

45. Defendant denies the allegations of paragraph 45.

46. Defendant denies the allegations of paragraph 46.

47. Defendant denies the allegations of paragraph 47.

48. Defendant denies the allegations of paragraph 48.

49. Defendant denies the allegations of paragraph 49.

C. P150003 PRODUCTS

50. Defendant denies the allegations of paragraph 50.

51. Defendant denies the allegations of paragraph 51.

52. Defendant denies the allegations of paragraph 52.

53. Defendant denies the allegations of paragraph 53.

54. Defendant denies the allegations of paragraph 54.

55. Defendant denies the allegations of paragraph 55.

56. Defendant denies the allegations of paragraph 56.

57. Defendant denies the allegations of paragraph 57.

58. Defendant denies the allegations of paragraph 58.

59. Defendant denies the allegations of paragraph 59.

60. Defendant denies the allegations of paragraph 60.

61. Defendant denies the allegations of paragraph 61.

V. COUNT II: INFRINGEMENT OF U.S. PATENT NO. 7,033,603 B2

62. Defendant repeats and re-alleges its answers to every allegation of the prior paragraphs as though set forth fully herein.

63. Defendant denies the allegations of paragraph 63, except that Defendant admits that the '603 Patent—titled “Drug Releasing Biodegradable Fiber for Delivery of Therapeutics”—was issued on April 25, 2006, by the United States Patent and Trademark Office to named inventors Kevin D. Nelson and Brent B. Crow, that the Board of Regents, The University of Texas System, is identified as assignee, and that a copy of the '296 Patent is attached to the Complaint as Exhibit C.

64. Defendant lacks knowledge or information regarding the allegations of paragraph 64 and, therefore, denies the allegations of this paragraph.

65. Defendant denies the allegations of paragraph 65, except that Defendant avers that the '603 Patent speaks for itself and refers the Court to the patent for its contents.

66. Defendant denies the allegations of paragraph 66.

67. Defendant denies the allegations of paragraph 67.

68. Defendant denies the allegations of paragraph 68.

69. Defendant denies the allegations of paragraph 69.

70. Defendant denies the allegations of paragraph 70, including the claim chart attached to the Complaint as Exhibit D.

A. MONORAIL™ CATHETER PRODUCTS

71. Defendant admits the allegations of paragraph 71.

72. Defendant denies the allegations of paragraph 72.

73. Defendant denies the allegations of paragraph 73.

B. SYNERGY™ OVER-THE-WIRE PRODUCTS

74. Defendant admits the allegations of paragraph 74.

75. Defendant denies the allegations of paragraph 75.

76. Defendant denies the allegations of paragraph 76.

C. P150003 PRODUCTS

77. Defendant admits the allegations of paragraph 77.

78. Defendant denies the allegations of paragraph 78.

79. Defendant denies the allegations of paragraph 79.

80. Defendant denies the allegations of paragraph 80.

81. Defendant denies the allegations of paragraph 81.

SEPARATE DEFENSES

Without any admission as to the burden of proof or as to any of the averments in the Complaint, Defendant sets forth the following separate defenses:

FIRST SEPARATE DEFENSE

Invalidity

The claims of the '296 Patent and the '603 Patent are invalid for failure to satisfy the requirements of the United States patent laws embodied in 35 U.S.C. § 100, et seq., including one or more of the following: 35 U.S.C. §§ 102, 103, and 112.

SECOND SEPARATE DEFENSE

Laches

UT is barred from relief under the doctrine of laches.

THIRD SEPARATE DEFENSE

Waiver

UT is barred from relief under the doctrine of waiver.

FOURTH SEPARATE DEFENSE

Reservation of Defenses

Defendant reserves all affirmative defenses under Fed. R. Civ. P. 8(c), the patent laws of the United States, and any other defenses at law or in equity, that may now or in the future be available based on discovery or any other factual investigation concerning this case.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Defendant demands a trial by jury for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Defendant prays that this Court enter judgment as follows, ordering that:

- (a) The Complaint is dismissed with prejudice and each request for relief therein is denied;
- (b) Each and every claim of U.S. Patent Nos. 6,596,296 and 7,033,603 is declared invalid;
- (c) Defendant is declared not liable for directly, contributorily, or inducing infringement of any claim of U.S. Patent Nos. 6,596,296 or 7,033,603;
- (d) UT pay to Defendant the costs and reasonable attorney's fees incurred by Defendant in this action; and
- (e) Defendant be granted such other and further relief as this Court deems just and proper.

DATED: May 11, 2020

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on May 11, 2020, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF (which will send notification that such filing is available for viewing and downloading to all registered counsel), and in addition caused true and correct copies of the foregoing document to be served upon the following counsel in the manner indicated:

For Plaintiffs, Board of Regents, University of Texas System and TissueGen, Inc.:

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May 11, 2020

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